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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,806

05/08/2006

Deepak Gandhi

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EXAMINER

STEWART, JASON-DENNIS NEILKEN

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

10/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,806	Applicant(s) GANDHI ET AL.	
	Examiner JASON-DENNIS STEWART	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :23 April 2007, 25 August 2008, 10 October 2008, 24 December 2008, 31 August 2009.

DETAILED ACTION

The following is a Non-Final Office action in response to communications received on 05/08/06. Claims 1-27 are currently pending and addressed below.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Drawings

2. The drawings are objected to because Figures 1A and 1B are difficult to view due to poor quality. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Allowable Subject Matter

3. Claims 5 and 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-14, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites a Markush group of possible alloys, and further describes the percentages of metals in each of the members of the Markush group without limiting the claim to a single alloy. This renders the claim indefinite.

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7. Claims 4-7 recites the limitation "platinum: tungsten alloy, platinum: rhodium: ruthenium alloy, platinum: rhodium alloy, and platinum: nickel alloy" respectively. There is insufficient antecedent basis for this limitation in the claims.

8. Claim 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the "ratio of the material" as written in Claim 25. The claim was examined as best understood.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-4, 7, 8, 10, 13-21, 24, 25, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Mayer 2003/0009215.

11. Mayer discloses a stent made up of a platinum: iridium alloy having about 70%-80% platinum and 20%-30% iridium (paragraph 76). Mayer also discloses a 90% platinum - 10% nickel alloy and a platinum – tungsten alloy containing 5-15% tungsten. Mayer discloses the enhanced radiopacity of the stent because of these materials (abstract). Mayer further discloses that the stent may be balloon expandable or self-

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expandable as is well known in the art (paragraphs 5 and 28). Mayer also discloses the use of biocompatible coatings on the surface of the stent device (paragraph 27).

Furthermore, Mayer discloses the use of a delivery catheter (paragraph 79) which encompasses balloon delivery catheters which are old and well known in the art for stent delivery as is there placement at the distal end of the catheter for deployment.

12. Regarding Claims 15 and 16, the limitation of the structure being formed by welding is a product-by-process limitation and holds not patentable weight.

13. Regarding Claim 19-21, the limitation of the deployed pressure, radial force, and deflection of the structure *in vivo* are functional limitations and holds no patentable weight in the absence of differentiating structure.

14. Regarding Claim 27, the limitation is a matter of design choice to provide minimal vessel injury, which would be the goal of any surgeon when implanting a stent into a vessel.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Alt 6,767,360.

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17. Mayer discloses the invention as claimed and as discussed above. However, Mayer does not explicitly disclose a stent having a sidewall thickness of less than 0.0035 inches.

Alt discloses that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, ll. 50-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer with the sidewall width of Alt since this is the typical strut width of a coronary stent as taught by Alt (col. 7, ll. 50-55).

18. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Alt 2004/0039438.

19. Mayer discloses the invention as claimed and as discussed above. However, Mayer does not explicitly disclose a stent having iridium oxide or titanium nitrate coatings as well as therapeutic coatings.

Alt discloses a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer with the coatings of Alt in order to prevent tissue irritation and deliver drugs locally in the body.

20. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Ferrera 2004/0193246.

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21. Mayer discloses the invention as claimed and as discussed above. However, Mayer in view of Palmaz does not explicitly disclose a stent having a specific compressed and uncompressed profile dimension.

Ferrera discloses a stent having a compressed delivery configuration of less than .02 inches (paragraph 58) in order to treat an aneurysm. Inherently, the uncompressed configuration would be greater than .02 inches. Furthermore, such limitations are merely a product of design choice based on the use of the stent.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Palmaz with the dimensions of Ferrara in order to treat an aneurysm as taught by Ferrara (abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738